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APPLICATION NO.	FILING DATE 07/30/2001	FIRST NAMED INVENTOR  D. Wade Walke	ATTORNEY DOCKET NO.  LEX-0208-USA	CONFIRMATION NO
I EXICON G	7590 12/13/2002 GENETICS INCORPORA IOLOGY FOREST PLACE		EXAMINER MURPHY, JOSEPH F	
THE WOODL	ANDS, TX 77381-1160		ART UNIT  1646  DATE MAILED: 12/13/200	PAPER NUMBER

Please find below and/or attached an Office communication concerning this application or proceeding.

·		Application	on No.	Applicant(s)
		09/918,35	59	WALKE ET AL.
Office Action Summary		Examiner		Art Unit
		Joseph E	Muroby	1646
	The MAILING DATE of this commu	nication appears on the	e cover sheet with	the correspondence address
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A SHC THE M - Extens after S - If the p - If NO - Failure	ORTENED STATUTORY PERIOD IAILING DATE OF THIS COMMUNITY (a) MONTHS from the mailing date of this corporated for reply specified above is less than thirty period for reply specified above, the maximum e to reply within the set or extended period for reply received by the Office later than three months of patent term adjustment. See 37 CFR 1.704(b).	NICATION.  In sof 37 CFR 1.136(a). In no expending the state of the st	vent, however, may a reply tutory minimum of thirty (3 vill expire SIX (6) MONTH	y be timely filed  (i0) days will be considered timely.  S from the mailing date of this communication.
1)⊠	Responsive to communication(s)	filed on 03 October 20	<u>002</u> .	
2a)□	- Contact Civil At	2h\⊠ This action is	s non-final.	. a
3)□ Dispositi	Since this application is in condit closed in accordance with the pro on of Claims	actice under Lx parts	pt for formal matte Quayle, 1935 C.D.	ers, prosecution as to the merits is 11, 453 O.G. 213.
41⊠	Claim(s) 1 and 5-9 is/are pending	g in the application.		
,	4a) Of the above claim(s) is	s/are withdrawn from o	consideration.	
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	Claim(s) 1 and 5-9 is/are rejected	I.		
7)[]	Claim(s) is/are objected to	).		
 8)∏	Claim(s) are subject to res	striction and/or election	requirement.	
Applicat	tion Papers			
9)[	The specification is objected to by	the Examiner.	الله يعال إلى الله الله الله الله الله الله الله ال	o Evaminer
10)[	The drawing(s) filed on is/a	are: a) ☐ accepted or b)	objected to by tr	nce See 37 CFR 1.85(a).
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11)[	Applicant may not request that any The proposed drawing correction	filed on is: a)	Office action	oobbio.a. av
	If approved, corrected drawings ar	e required in reply to this	Onice action.	
	The oath or declaration is objecte			
Priority	under 35 U.S.C. §§ 119 and 120		dea 05 U 0 0 3	s 119(a)-(d) or (f)
13)[	Acknowledgment is made of a c	laim for foreign priority	unaer 35 U.S.C.	g 113(a)=(a) or (i).
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	1. Certified copies of the pri	ority documents have t	been received.	natication No.
	2.☐ Certified copies of the pri	ority documents have I	been received in A	received in this National Stage
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1) 🔲 N	otice of References Cited (PTO-892) otice of Draftsperson's Patent Drawing Rev oformation Disclosure Statement(s) (PTO-1	view (PTO-948) 449) Paper No(s) <u>5</u> .	5) Notice of	y Summary (PTO-413) Paper No(s)  f Informal Patent Application (PTO-152)  Sequence Comparison A .
	and Trademark Office	5.00 A.11 . 5.		Part of Paper No. 8

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## **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of Group III in Paper No. 7, 10/32002 is acknowledged.

### Specification

The title of the invention is not descriptive. Applicant should avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

Claim Rejections - 35 USC § § 101, 112, first paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-9 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed patentable utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

It is clear from the instant specification that the nucleic acid encoding the NHP polypeptide has been isolated because of its similarity to known proteins. However, it is commonly known in the art that sequence-to-function methods of assigning protein function are

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prone to errors (Doerks et al.1998). These errors can be due to sequence similarity of the query region to a region of the alleged similar protein that is not the active site, as well as homologs that did not have the same catalytic activity because active site residues of the characterized family were not conserved (Doerks et al. page 248, column 3, fourth and fifth paragraphs). Inaccurate use of sequence-to-function methods have led to significant function-annotation errors in the sequence databases (Doerks et al. page 250, column 1, third paragraph). Furthermore, Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs must have different molecular and cellular functions. Finally, Bork et al. (1996, Trends in Genetics 12:425-427) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts.

After complete characterization, this protein may be found to have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (Sup. Ct., 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation.

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However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 USC § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a nucleic acid encoding a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as NHP, the instant invention is incomplete. In the absence of knowledge of the natural substrate or biological significance of this protein, there is no immediately obvious <u>patentable</u> use for it. To employ a protein of the instant invention in the identification of substances which inhibit its activity is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real world" use for NHP then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

Claims 1, 5-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Even if, arguendo, the nucleic acid encoding the NHP protein is found to have a patentable utility, claim 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding an amino acid of SEQ ID NO: 7, or a nucleic acid with the sequence as set forth in SEQ ID NO: 6, does not reasonably provide enablement for a nucleic acid which hybridizes to SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 5 are overly broad since insufficient guidance is provided as to which of the myriad of variant nucleic acids encode polypeptides which will retain the characteristics of NHP. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of NHP. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the claims encompass variant nucleic acids and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to make and use the claimed invention. See In re Wands, 858 F.2d at 737, 8

Page 6 Application/Control Number: 09/918,359 Art Unit: 1646 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below: (1) the breadth of the claims - The claims are drawn to a nucleic acid which hybridizes to

- SEQ ID NO: 6.
- (2) the nature of the invention The instant invention is a nucleic acid which hybridizes to SEQ ID NO: 6.
- (3) the state of the prior art The Voet reference demonstrates that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.
- (5) the level of predictability in the art The Voet reference demonstrates the unpredictability of the protein art.
- (6) the amount of direction provided by the inventor Applicant has only taught a nucleic acid with a sequence as set forth in SEQ ID NO: 7, and the polypeptide of SEQ ID NO: 7.
  - (7) the existence of working examples Working examples are not provided for NHP.
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 5 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

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Claims 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. The claims are drawn to a nucleic acid which hybridizes to SEQ ID NO: 6. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the encoded SEQ ID NO: 7. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid with a sequence as set forth in SEQ ID NO: 6, and the polypeptide of SEQ ID NO: 7 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative

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number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

## Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the term "highly stringent conditions", which is a conditional term and renders the claim indefinite. The metes and bounds of the claim thus cannot be ascertained.

This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be "highly stringent".

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (1997).

The EST AA309878 is a nucleic acid which is 28.5% identical to SEQ ID NO: 6, and would hybridize to SEQ ID NO: 6 under "highly stringent conditions, see Sequence Comparison A, attached. Thus claim 5 is anticipated.

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#### Conclusion

No claim is allowed.

## Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.

Patent Examiner

Art Unit 1646

December 10, 2002

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DEFINITION
ACCESSION
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RS Adams, M.D., Kerlavage, A.R., Fleischmann, R.D., Fuldner, R.A., White, C.J., Lee, N.H., Kirkness, E.F., Weinstock, K.G., Gocayne, J.D., White, C.J., Lee, N.H., Kirkness, E.F., Weinstock, K.G., Gocayne, J.D., White, C.J., Lee, N.H., Kirkness, E.F., Weinstock, K.G., Gocayne, J.D., White, C.J., Clayton, R.A., C., Sutton, G., Blake, J.A., Brandon, R.C., Man-Mal, C., Clayton, R.A., L.M., Fitzhugh, W.M., Fritchman, J.L., Geoghagen, N.S., Glodek, A., L.M., Fitzhugh, W.M., Fritchman, J.L., Geoghagen, N.S., Glodek, A., Kelley, J.C., Liu, L.-I., Marmaros, S.M., Merrick, J.M., Kelley, J.C., Liu, L.-I., Marmaros, S.M., Merrick, J.M., Relley, J.M., Kelley, J.C., Liu, L.-I., Marmaros, S.M., Merrick, J.M., Pelligrino, S.M., Moreno-Palanques, R.F., McDonald, L.A., Nguyen, D.T., Pelligrino, S.M., Phillips, C.A., Ryder, S.E., Scott, J.L., Saudek, D.M., Shirley, R., Phillips, C.A., Ryder, S.E., Scott, J.L., Saudek, D.M., Shirley, R., Bednarik, D.P., Cao, L., Cepeda, M.A., Coleman, T.A., Collins, E.J., Bednarik, D.P., Cao, L., Cepeda, M.A., Coleman, T.A., Collins, E.J., Musch, C., Feng, D.-F., Ferrie, A., Fischer, C., Hastings, G.A., He, W., Hu, J.S., Greene, J.M., Gruber, J., Hudson, P., Kim, A.K., Kozak, D.L., Kunssh, C., Hungjun, J., Li, H., Meissner, P.S., Olsen, H., Raymond, L., Mei, Y.F., Wing, J., Xu, C., Yu, G.L., Ruben, S.M., Dillion, P.J., Fannon Wei, Y.F., Wing, J., Xu, C., Yu, G.L., Ruben, S.M., Dillion, P.J., Fannon Wei, Y.F., Wing, C.A., Haseltine, W.A., Fields, C., Fraser, C.M. and
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Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo
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Contact: Kerlavage, AR
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Email: arkerlav@tigr.
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/clone_lib="Jurkat T-cells V"
/cell_type="T-lymphocyte"
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     1266 TCTGGCCCTGATTCTGGAGAACTTCCTTCACAAGTGGGACCCCGCAGCCACCTGCAGCC 1325
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775 CCGTTGTCCTGCTGGAGGCCGGAGATGGTGGGCCTGCTGTCGCTGTGGGACATGACCCGC 834
                                                                                                                                                               Local Similarity
                                                                      8 CCGCACTCAGGATGGAAGCCAGAGCAGTATGGCCCACTGTCGCTCTGGGACATGACACGA 67
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           BF537032 994 bp mRNA linear EST 11-DEC-2000 602048936F1 NCI_CGAP_SG2 Mus musculus cDNA clone IMAGE:4188321 5',
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           BF537032.1 GI:11624400
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                mRNA sequence
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          Email: cgapbs-r@mail.nih.gov
Tissue Procurement: Jeffrey E. Green, M.D.
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            Contact: Robert Strausberg, Ph.D.
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
Mammalia; Eutheria; Rodentia; Sciurognathi; Muridae; Murinae; Mus
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             Unpublished (1999)
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           National Institutes of Health, Mammalian Gene Collection (MGC)
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               DNA Sequencing by: Incyte Genomics, Inc. Clone distribution: MGC clone distribution information can be found through the I.M.A.G.E. Consortium/LLNL at:
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Plate: LLAM9512 row:
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                                                                                                                                               Conservative
                                                                                                                                                                                                                                       /clone="IMAGE:4188321"
/clone="Ib="NGI_CGAP_SG2"
/clone_lib="NGI_CGAP_SG2"
/clone_lib="NGI_CGAP_SG2"
/clone_sib="NGI_CGAP_SG2"
/note="Organ: sallvary gland; Vector: pCMY-SPORT6; Site_1: Note="Organ: sallvary gland; Vector: pCMY-SPORT6; Site_1: Note="Solid Constructed by Life dr. Average insert size 1.3 kb. Constructed by Life dr. Average insert size 1.3 kb. Constructed by Life Technologies. Note: this is a NCI_CGAP Library."

Technologies. Note: this is a NCI_CGAP Library."

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                                                                                                                                                                                                                                                                                                                                                                                                          /strain="FVB/N"
                                                                                                                                                                                                                                                                                                                                                                                                                          /organism="Mus musculus"
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76.5%;
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                                                                                                                                                     Score 390; DB 10; Length 994; pred. No. 2.2e-75; o; Mismatches 145; Indels 16;
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